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August 6, 2019

VIA ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, NJ 08101

RE: *In re Valsartan Products Liability Litigation*, No. 1:19-md-02875

Dear Judge Schneider:

We are writing to advise the court of the status of the Defendants' core discovery productions, pursuant to the Court's April 29, 2019 Order (D.E. 88) (hereafter "Court's Order") and CMO Nos. 7 and 10.

Background

On June 27, 2019, the deadline delineated in the Court's Order, Defendants made an initial production of documents to Plaintiffs, which consisted primarily of ANDA files. Defendants supplemented these productions on July 19, 2019, and. additional supplemental productions and/or corrections to previous productions were received on July 20, July 30, and August 6, 2019. In total, all Defendants have produced approximately 22,000 documents. Plaintiffs have worked expeditiously to review the documents in order to identify and address the fundamental issues.

In a July 17, 2019 e-mail to Defendants, Plaintiffs identified some preliminary global issues and requested a meet and confer. In a July 31, 2019 letter to Defendants, Plaintiffs identified

serious deficiencies and gaps contained in the Defendants' core discovery productions and requested a meet and confer with all the Defendants to address these deficiencies. A number of the deficiencies in the productions demonstrated a fundamental difference in opinion as to the scope and intent of the Court's Order and the form and content of the productions required therein. On August 1, 2019, Plaintiffs supplemented their July 31, 2019 letter with one additional issue. A meet and confer conference call was then scheduled for Friday August 2, 2019. Prior to the August 2, 2019 conference call, Defendants e-mailed a short response to a few of the global items identified in Plaintiffs' deficiency letters.

Plaintiffs expected that all issues would be addressed on this meet and confer call in light of the approaching August 6, 2019 deadline to submit this letter to the Court. Accordingly, Plaintiffs had seven members of the Executive Committee on the call, including three of the co-leads. In contrast, only Mr. Goldberg and Ms. Priselac attended this important conference call for the defense. Further, Mr. Goldberg informed Plaintiffs that he had no authority to discuss any of the deficiencies that did not directly pertain to his own clients, Prinston Pharmaceutical, Zhejiang Huahai Pharmaceutical, and Solco. No other defense attorney attended. Mr. Goldberg then advised that he could not even address the deficiencies identified for his own clients and offered to discuss his clients' deficiencies on Monday, August 5, 2019. Mr. Goldberg informed Plaintiffs' counsel that any issue that did not pertain to all Defendants would have to be taken up individually with counsel for each individual Defendant's counsel.

Plaintiffs were then contacted via e-mail by Aurobindo's and Teva's counsel on August 2, 2019 to schedule individual meet and confers, and received written responses from Prinston and Hetero USA, Inc. on August 5, 2019 and Aurobindo on August 6, 2019. Despite receiving Plaintiffs' deficiency letters, no other defendant has responded. As such, many of the below delineated issues remain unaddressed and unresolved as of the writing of this letter.

Requests to All Defendants

With respect to ANDA productions, Plaintiffs' research has uncovered several ANDAs which contain the adulterated Valsartan API that were not produced, despite being the subject of FDA scrutiny in the wake of the recalls. Similarly, it is clear that numerous Defendants have identified a subset of manufacturing facilities as being relevant, and have declined to produce inspection reports and associated correspondence from the FDA relating to other manufacturing facilities operated by Defendants. Plaintiffs are entitled to know Defendants' understanding of the relevant ANDA files, DMF Files, and Manufacturing facilities. In the August 2, 2019 meet and confer with Defendants' liaison counsel, Mr. Goldberg indicated that Defendants position was that they were not required, under the four corners of the Court's Order, to produce this information.

Next, the Court's April 29, 2019 Order requires production of the core discovery with regard to both the facilities that manufactured the API, and the facilities that manufactured the

finished products – the finished drug manufacturers. The defense reads the Order to only address API facilities, despite the language of the Order identifying both. This is a fundamental disagreement that will need to be resolved by the Court.

Similarly, Defendants have apparently taken the position that documents located at related entities need not even be attempted to be obtained and produced, even if the particular defendant may have the ability to do so. However, in the District of New Jersey, control is liberally construed and is based on whether the corporate relationship "establishes some legal right, authority ***or ability*** to obtain the requested documents on demand." *Camden Iron & Metal, Inc. v. Marubeni Am. Corp.*, 138 F.R.D. 438, 442 (D.N.J. 1991) (emphasis added). Plaintiffs have identified in the section related to individual defendants, below, where this interpretation is a particularly problematic issue.

In addition, the production letters fail to comply with the Order, since they do not, "identify the bates numbers of the documents responsive to each category of documents in paragraph 6 herein." For example, although Defendants generally identified groups of documents as containing FDA correspondence, they did not identify which documents were produced in response to each of the categories as ordered by the Court, such as those pertaining to category (3) - efforts to contain, remove or detect the contamination or category (4) - supplements to the Valsartan Drug Master File re: manufacturing process changes from 2010 to present.

Defense counsel advised us on August 2, 2019 that this requirement is unreasonable, and they will not do so since it would be burdensome. This issue was argued, and the Order is explicit. The failure to comply leaves Plaintiffs to speculate and be uncertain as to what specific documents respond to each category in the Order. The Defendants should be ordered to comply and provide the bates ranges as ordered. In order to attempt to address these failures to comply with the Court's Order, in their July 31, 2019 letter, Plaintiffs requested additional information from each Defendant to help Plaintiffs determine whether the production of core discovery was in compliance. These requests were as follows:

- A comprehensive list of all ANDA applications submitted to the FDA by each Defendant which referenced or incorporated the adulterated Valsartan API. This list should specifically identify the ANDA applications which Defendants have affirmatively chosen not to produce, and Defendants' justification for not producing those ANDA files, and/or any correspondence with the FDA regarding those ANDA applications. This information was requested as it appeared that at least some defendants had not produced all ANDAs.

- A comprehensive list of all manufacturing facilities which are involved in the manufacturing of the adulterated Valsartan-containing drugs ("VCDs"), including finished dose manufacturing, and testing facilities. This list should specifically identify those facilities involved in the manufacturing of finished VCD for which Defendants

affirmatively chose not to produce correspondence with the FDA related to inspections (as required in ¶ 6(a)(3)(5) of the Court's discovery order), and Defendants' justification for that decision. This information was requested as it appeared that some facilities were being withheld.

- A comprehensive list of all testing conducted on the Valsartan products, and the corresponding bates ranges for those results provided in Defendants' production of Core Discovery. This information was requested as it appeared that many defendants produced minimal testing related documents. At the very least, as requested on August 2, 2019, Defendants should disclose whether the FDA communications reference all testing that has been conducted – defense counsel advised that it is Plaintiffs' burden to figure that out, which is not a reasonable position and is characteristic of much of the back and forth.

Plaintiffs have also not received any substantive response to their e-mail dated July 17, 2019 regarding ESI production of certain FDA submissions, and requesting that Defendants produce these files in eCTD format. Defendants' failure to produce ANDA files in the eCTD format has significantly slowed and limited Plaintiffs' ability to review those ANDAs and to ensure they are complete.

Finally, there are some Defendants subject to the Court's order who have not produced any documents, and no reason has been provided for such failure to produce (e.g. the entity contends it has not been properly served). Therefore, it is difficult for Plaintiffs to determine whether all Defendants who are required to produce documents have complied with the Court's Order.

Defendant Specific Deficiencies

Prinston/Zhejiang Huahai Pharmaceutical/Solco

Plaintiffs observe that Zhejiang Huahai Pharmaceutical did not directly produce core discovery documents. Defendants' requested that Prinston confirm that all documents responsive to the core discovery requests in the possession, custody, or control of Zhejiang Huahai Pharmaceutical have been produced through Prinston and Solco. Second, if Zhejiang Huahai Pharmaceutical documents were produced through Prinston and Solco, Plaintiffs requested an explanation as to why they were produced together and why there is no separate Bates label for Zhejiang Huahai Pharmaceutical documents. These issues have not yet been addressed by Defendants.

Plaintiffs also identified a subset of other specific deficiencies with Prinston's production to which Prinston responded in writing on August 5, 2019 by addressing the Defendant specific deficiencies and agreeing to search for and produce additional documents. Plaintiffs will advise

the Court if any issues remain with Prinston other than the global issues applicable to all Defendants.

Mylan

Plaintiffs identified the following deficiencies with Mylan's production July 31, 2019. As of August 6, 2019, Counsel for Mylan has not reached out to Plaintiffs to respond to these deficiencies or to schedule a meet and confer.

1. **Failure to comply with ¶ 6(a)(1) of the Court's Order (ANDA file production).** Mylan failed produce the ANDA file for its Amlodipine Valsartan HCTZ product (ANDA 20473), which ultimately did not receive FDA approval. The FDA's denial of this ANDA application was a result of contamination issues and is highly relevant to the claims at issue. *See* MYLAN-MDL2875-00029879. Mylan has not responded to Plaintiffs' Letter.

2. **Failure to comply with ¶ 6(a)(3)(2) of the Court's Order (testing documents).** Production included testing results based on API batch numbers but there is no corresponding document identifying results based on US NDC code/lot number. Mylan has not responded to Plaintiffs' Letter.

3. **Failure to comply with ¶ 6(a)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Mylan failed to provide "all FDA Form 483s, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding Defendants' responses to same, regarding any facility that manufactured or supplied the API at issue." Specifically, Mylan failed to produce the following:

    a. Inspection reports, Form 483s, warning letters, EIRs, or correspondence between Mylan and the FDA related to inspections of the Nashik, India facility (e.g., September 2016 inspection which resulted in a Warning letter; April 2017 Warning letter; November 2018 inspection which resulted in a Warning letter).

    b. Inspection reports, Form 483s, warning letters, EIRs, or correspondence between Mylan and the FDA related to inspections of the Morgantown, WV facility (e.g., inspections that occurred in November 2016, March and April 2018).

    Both of these facilities played critical roles in the manufacturing of Mylan's adulterated Valsartan products and are referenced throughout the ANDA submissions to the FDA for Mylan's various Valsartan products and are relevant to the claims and issues in this litigation. Mylan has not responded to Plaintiffs' letter.

4. **Failure to comply with ¶ 6(a)(3)(6) of the Court's Order (list of customers).** Mylan failed to provide customer lists that identified customers who received its products from the time its Valsartan HCTZ product entered the market in 2012. The list of customers produced by Mylan only listed wholesale distributors who, at the time of the valsartan recall, had adulterated product in their stores. Mylan has not responded to Plaintiffs' letter.

5. **ESI Deficiencies.** Documents produced with .xsl; .xml; .joboptions; .dtd; and .txt format appear to display as coding or a series of letters and numbers.

Hetero

Hetero's production correspondence indicated that it was "working with Hetero USA to identify and produce further documents in its possession concerning communications with the FDA relating to the ARB recall" and that additional documents would be produced on a rolling basis. Plaintiffs never received a subsequent production and, as of August 6, 2019, counsel for Hetero continues to maintain the same position, without having produced any additional documents.

Plaintiffs have further identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 6(b)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Hetero USA failed to provide "all FDA Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue." Plaintiffs are aware of several investigations by the FDA of Hetero's facilities, including inspections on or around December 2016 and February 2018. One of these investigations resulted in a warning letter sent by the FDA on August 15, 2017.

   Hetero USA's response on August 5, 2019 stated that to the extent any further documents are located in Hetero USA's possession, they will be produced in a supplemental production at an unspecified time. Hetero further claimed that to the extent additional documents are located at Hetero Labs in India, that it has informed Hetero Labs of the existence of the lawsuit, but has refused to produce any documents not in its "possession."

   Plaintiffs maintain the "possession" is not the standard for production, and Hetero USA, Inc. has made no showing that it does not have the ability to produce these documents, as required under the law in this District.

2. **Failure to comply with ¶ 6(b)(3)(2) of the Court's Order (testing documents).** Hetero's Production included testing results based on API batch numbers but there is no

corresponding document identifying results based on US NDC code/lot number. In addition, there are no documents identifying whether and to what extent API batches were combined to create pills distributed in the US. Hetero has not responded to Plaintiffs' request for confirmation that Hetero has produced all testing results contained within its possession, custody or control.

Hetero USA's response to this deficiency is the same as for item 1.

3. **Failure to comply with ¶ 6(b)(3)(6) of the Court's Order (list of customers).** Hetero USA failed to provide "a list of all United States customers from 2010 to present."

   Hetero USA's response is that customer lists may be in the possession of co-Defendant Camber. Hetero makes no representation that it attempted to obtain this information, nor that it has no ability to do so, which does not comply with the law in this District.

4. **ESI Deficiencie**s. Plaintiffs identified a number of deficiencies in the production involving corruption, improperly produced documents, etc. Hetero USA has stated that it has addressed these issues in a revised production sent today. Plaintiffs are in the process of loading that production and will work with Hetero USA to resolve any remaining issues.

Aurobindo

In their cover letter enclosing their production, Aurobindo (the US entity) indicated that the documents responsive to Paragraph 6(a) were located at Auro Limited in India, which has not yet been served, and consequently Aurobindo was not producing any documents from Auro Limited, nor had made any attempt to do so. Plaintiffs maintain the "possession" is not the standard for production, and Aurobindo has made no showing that it does not have the ability to produce these documents, as required under the law in this District.

Aurobindo provided a written response to Plaintiffs' deficiency letters on August 6, and the parties were able to further meet and confer the same afternoon. Other than the issues applicable to all Plaintiffs, and the issue with whether or not the United States entity has an obligation to attempt to obtain documents from the Indian entity, the Parties believe they will be able to resolve the remaining issues.

Teva

Counsel for Teva emailed Plaintiffs on August 5, 2019 in response to Plaintiffs' July 30, 2019 letter providing a time for a call on August 6, 2019. During this call, Teva's counsel was unable to provide any substantive response to the deficiencies identified in Plaintiffs' letters, and, instead, stated that he will look into these issues and follow up with Plaintiffs.

In addition to the more specific deficiencies Plaintiffs identify below, Teva objects as to relevance/responsiveness on approximately 52 documents (specifically cover letters or emails) from the custodial file of Constance Truemper, Teva's regulatory compliance manager. These documents often include situations where the cover email has been withheld as "not-responsive" but the attachments are all part of Teva's production of correspondence with the FDA regarding this very recall. *See* TEVA-MDL2875-00004316. Given the fact that the supposedly "irrelevant" document often attaches dozens of highly relevant documents, Plaintiffs challenged the propriety of this relevance redaction, and demanded production of these cover emails. After the August 6, 2019 meet and confer call, Teva's counsel responded via e-mail to confirm its position that it maintains these cover e-mails are "irrelevant" and not required to be produced under the terms of this Court's Order. Plaintiff disputes this interpretation of the Court's Order.

Beyond these relevancy determination issues, Plaintiffs have identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 6(b)(1) of the Court's Order (ANDA file production).** Teva did not produce documents for ANDA 090642 and ANDA 077530. Both of these ANDAs were the subject of an information request by the FDA to Teva about NDMA contamination. *See* TEVA-MDL2875-00004067 and TEVA-MDL2875-00004486). Furthermore, for the ANDA files which Teva did produce documents, Teva's production related to ANDA 91235 appears to be woefully inadequate. More specifically, Documents in the ANDA file refer to amendments and/or submissions which occurred on the following dates, for which Teva has produced no documents/supplements or submissions: December 30, 2008, April 3, 2009 October 2, 2009, March 12, 2010, June 16, 2010, July 30, 2010, December 30, 2010. Teva has not provided a substantive response to Plaintiffs' letters.

2. **Failure to comply with 6(b)(2) of the Court's Order (testing results).** Production of product testing results appears to be incomplete. We have identified a single document with testing data beginning at Bates TEVA-MDL2875-00004668. Based on our review, Teva has failed to produce testing results for NDMA for multiple drugs and NDEA levels for all drugs. Teva has not provided a substantive response to Plaintiffs' letters.

3. **Failure to comply with ¶ 6(b)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Teva failed to produce any documentation whatsoever regarding inspection reports, Form 483s, EIRs, cGMP inspection reports, warning letters or responses Indeed, Teva's ANDA submissions lists the Jerusalem Oral Solid Dose ("OSD") facility as the location where the manufacturing of the Valsartan products will occur. *See* TEVA-MDL2875-00003557. Teva received a warning letter for this facility in 2010, citing cGMP deficiencies related to laboratory reporting and systems. Teva has not provided a substantive response to Plaintiffs' letters.

4. **Failure to comply with ¶ 6(b)(3)(6) of the Court's Order (list of customers**). Teva failed to provide customer lists that identified customers who received its valsartan products from the time they first entered the market. The list of customers produced by Teva only identifies customers with non-expired product, but does not include customers who received product that had previously expired. Teva has not provided a substantive response to Plaintiffs' letters.

Torrent

In their July 17, 2019 e-mail and July 31, 2019 letter, Plaintiffs requested that Torrent identify the location of responsive documents, to the extent that Torrent did not produce these documents in their core discovery. Torrent has not responded to this request.

Beyond this fundamental issue, Plaintiffs have identified the following more specific production deficiencies:

1. **Failure to comply with ¶ 5 of the Court's Order by identifying the specific bates ranges for each category of document in its cover letter enclosing production.** Torrent did not produce a cover letter with its initial production of documents. It then produced a single cover letter with the July 19, 2019 production, which remains deficient for the reasons articulated below.

2. **Failure to comply with ¶ 6(b)(3)(1) of the Court's Order (correspondence regarding the ARB recalls).** There appear to be significant gaps in Torrent's production of its FDA Correspondence. For example, only eight (8) FDA correspondence documents have been produced for the month of October 2018, five (5) for the month of November 2018, and a mere three (3) for the month of January 2019. It is unlikely that there were no further communications between Torrent and the FDA during this time period given the information which Plaintiffs were able to locate and those which are publicly available from the FDA showing numerous additional recalls[1]. Torrent has not responded to Plaintiffs' letter.

3. **Failure to comply with ¶ 6(b)(3)(2) of the Court's Order (testing).** The production included a single table of test results for all non-expired lots [TORRENT-MDL2875-00001294] with API lot numbers but there is no corresponding document identifying results based on US NDC code/lot number. Torrent has not responded to Plaintiffs' letter.

[1] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan

4. **Failure to comply with ¶ 6(a)(3)(2) of the Court's Order (investigation into the cause of the alleged contamination).** Torrent has produced only *one* response to one FDA information request regarding NDMA contamination in the four Valsartan products (specifically ANDA 202377). However, Torrent has multiple other Valsartan ANDA's (including ANDA 201593, ANDA 091654, and ANDA 202728), for which it has failed to produce the FDA request or its responses. Torrent has not responded Plaintiffs' letter.

5. **Failure to comply with ¶ 6(b)(3)(5) of the Court's Order (facility inspection reports, documents and correspondence).** Torrent has failed to produce any form 483s related to their manufacturing facilities. For example, Sipra labs was inspected in September of 2011, and evidence indicates that the FDA issued a Form 483 to Torrent. *See*TORRENT-MDL2875-00003444). However, Torrent failed to produce this form 483 in their production.

6. **Failure to comply with ¶ 6(b)(3)(6) of the Court's Order (list of customers**). Torrent produced one document responsive to the Court's Core Discovery Order for Customer Lists from 2010-Present. This document's (Bates No. TORRENT-MDL2875-00004218) metadata states that it was created on October 1, 2015 and it was then modified August 16, 2018. The Court's Core Discovery Order specifically states that Torrent must produce customer lists from 2010-Present. Torrent has not responded to Plaintiffs' letter.

Thank you for your consideration.

Respectfully,

ADAM M. SLATER

AMS